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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/483,434	01/14/2000	JEFFERY L. MILLER	14014.0360	8390

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Gwendolyn D. Spratt, Esq.  
Needle & Rosenberg, P.C.  
The Candler Building  
127 Peachtree Street, N.E., Suite 1200  
Atlanta, GA 30303-1811

EXAMINER

LEFFERS JR, GERALD G

ART UNIT PAPER NUMBER

1636

DATE MAILED: 11/26/2001

14

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/483,434	MILLER ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Gerald Leffers	1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 27 August 2001.
- 2a) This action is **FINAL**.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-5 and 7-18 is/are pending in the application.
- 4a) Of the above claim(s) 4,5,8,11-14 is/are withdrawn from consideration.
- 5) Claim(s) 9 and 10 is/are allowed.
- 6) Claim(s) 1,2,15 and 16 is/are rejected.
- 7) Claim(s) 3,7,17,18 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)                  4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)                  5) Notice of Informal Patent Application (PTO-152)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                  6) Other: \_\_\_\_\_

## DETAILED ACTION

Receipt is acknowledged of applicants' response, filed 8-27-01 as Paper No. 13, wherein claim 9 was amended.

Claims 1-5 and 7-18 are pending in this application, with claims 4-5, 8 and 11-14 withdrawn from consideration as being drawn towards separate inventions. Because no new grounds of rejection are made in the instant action, the action is FINAL.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2 and 15-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This rejection is maintained for reasons of record in Paper No. 11.**

### ***Response to Arguments***

Applicant's arguments filed in Paper No. 13 have been fully considered but they are not persuasive with regard to the instant claims. Applicants' response essentially argues: 1) teachings incorporated by reference in the instant specification provide sufficient description of receptor/ligand pairs and methods of conjugating different biomolecules to describe the broad genus of methods encompassed by the instant claims, 2) the state of the art at the time of

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applicants' invention was sufficiently developed to allow one of skill in the art to envision a sufficient number of different embodiments of the claimed invention as to describe the broad genus of methods embraced by the rejected claims, 3) that the specification is enabling in view of the prior art and the teachings of the specification. In support of these arguments, applicants have provided copies of several references (Exhibits A-K). Each of these references has been considered in full (see the attached PTO-892).

Applicants' arguments regarding the description provided by references incorporated into the instant specification concerning conjugation of avidin or biotin to biomolecules other than proteins or nucleic acids were persuasive. The rejections of claims 3 and 17 have therefore been withdrawn.

With regards to assertions directed towards enablement of the claimed invention (e.g. Paper No. 13, page 10, last paragraph), it is noted that the instant rejection is for lack of description in the specification such that one of skill in the art would not recognize that applicants were in possession of the claimed invention. Arguments regarding enablement are not relevant to the instant rejection.

There are at least three essential elements of applicants' invention for delivery of active biomolecules to a cell. These include identification of "ligand"/"receptor" pairs suitable for use in the claimed invention, covalent attachment of the "receptor" to the surface of the cell and complexing the desired biomolecule with the ligand. Each of the references submitted by applicants directed towards characterization of receptor/ligand pairs does so in the context of natural receptors that are already present on the surface of the cell. For example, the teachings of Keusch, Karlsson et al and Spear et al are all directed towards native receptors (e.g. microbial

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pathogen receptors). The concept of designing ligands such that one can interfere with the infection process of a pathogen (i.e. “mopping up”) does not adequately address the issue of covalently attaching a biomolecule to the surface of a cell to generate a receptor. Each of the references submitted by applicants directed towards methods of conjugating different biomolecules are directed towards doing so in free solution. None of the teachings appear to be directed towards conjugation of a biomolecule to the surface of a cell. It is unclear whether any of the methods taught by the cited references for biomolecules other than biotin or avidin would be compatible with cell survival, for example.

The novelty of applicants’ invention appears to lay in the concept of covalently attaching a binding partner from a pair of biomolecules to the surface of a cell in order to generate an artificial receptor. The references supplied by applicants only provide a general outline of how receptor/ligand pairs interact and for how to covalently conjugate different biomolecules. There is no basis for one of skill in the art to extrapolate from these general teachings to envision specific embodiments of the claimed invention that would be functional (i.e. specific artificial receptors and their methods of construction). For example, nowhere in the specification is there an indication that applicants contemplated embodiments wherein a portion of a natural receptor is covalently attached to the surface of the cell in a manner such that it can bind a cognate ligand. Which portions of such a native receptor would be suitable for such covalent attachment to other biomolecules on the surface of the cell? To which constituent of the cell surface would they be attached and by what method that is compatible with cell survival?

Given that the descriptions provided by the references cited in applicants’ response are only directed towards general concepts of receptor/ligand interactions and covalent conjugation

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of different biomolecules and do not address the critical essential element of applicants' invention (i.e. covalent attachment of a biomolecule to the surface of a cell such that the biomolecule can act as an artificial receptor for a ligand/biomolecule complex), one of skill in the art would not have been able to envisage a representative number of specific embodiments of the claimed methods to describe the extremely broad genus. Therefore, despite the arguments made in applicants' response, one of skill in the art would have reasonably concluded applicants were not in possession of the claimed invention.

### *Conclusion*

Claims 9-10 are allowed. Claims 1-2, 15-16 are rejected. Claims 3, 7, 17 and 18 are objected to as being dependent upon a rejected claim. If rewritten as independent claims comprising each of the limitations of the claims upon which they are currently dependent, claims 3, 7, 17 and 18 would be allowable.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Schwartzman, Ph.D can be reached on (703) 308-7307. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gerald G Leffers Jr.  
Examiner  
Art Unit 1636

*[Signature]*  
ggl  
November 14, 2001

DAVID GUZO  
PRIMARY EXAMINER  
*David Guzo*